

REMARKS

I. Introduction

With cancellation without prejudice of claim 2 herein, claims 1 and 3 to 60 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

Applicants note with appreciation the acknowledgment of the claim for foreign priority and the indication that all of the certified copies of the priority documents have been received.

II. Rejection of Claims 1 to 9 and 53 to 60 Under 35 U.S.C. § 112

Claims 1 to 9 and 53 to 60 were rejected under 35 U.S.C. § 112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

With respect to the recitation of “adapted to” in claim 1 line 9, the Office Action contends that “[i]t has been held that the recitation that an element is ‘adapted to’ perform a function is not a positive limitation but only requires the ability to so perform [and thus] does not constitute a limitation in any patentable sense.” Office Action at p. 2. Applicants refer to Section 2173.05(g) of the Manual of Patent Examining Procedure (“MPEP”), which states that “[t]here is nothing inherently wrong with defining some part of an invention in functional terms” and “[f]unctional language does not, in and of itself, render a claims improper.” Also see *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), which is referenced in Section 2173.05(g) of the MPEP. In addition, Section 2173.05(g) of the MPEP refers to *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976), which court held that limitations such as “members adapted to be positioned” (emphasis added), were not improper. Thus, Applicants maintain that the recitation in claim 1 of “an outer sealing ring thereon which is adapted to engage and seal with the annular sealing face” is proper.

With respect to claim 1, line 9, the Office Action contends that the term “the annular sealing face” lacks antecedent basis. Claim 1 has been amended herein without prejudice to recite “the annular outer sealing face”.

With respect to claim 4, line 6, the Office Action contends that the term “the gripping jaw” lacks antecedent basis. Claim 4 has been amended so as to depend from claim 3 instead of cancelled claim 2. Claim 3 recites “a gripping jaw”. Therefore, the term “the gripping jaw” has proper antecedent basis.

With respect to the recitation of “adapted to” in claim 53, line 2 and in claim 54, lines 9 and 12, Applicants maintain that the recitation of “adapted to” is proper as more fully set forth above.

In view of the foregoing, it is respectfully submitted that claims 1, 3 to 9 and 53 to 60 fully comply with the requirements of 35 U.S.C. § 112, and withdrawal of this rejection is therefore respectfully requested.

III. Rejection of Claims 1 to 13, 15 to 28, 30, 31 and 33 to 60 Under 35 U.S.C. § 102(b)

Claims 1 to 13, 15 to 28, 30, 31 and 33 to 60 were rejected under 35 U.S.C. 102(b) as anticipated by International Patent Publication No. WO89/00952 (“Dufrene”). Applicants respectfully submit that Dufrene do not anticipate the present claims for the following reasons.

Claim 1 as amended relates to a method of aseptically filling an internally sterilized sealed container having a transfer port which comprises a tubular body which is sealed to the wall of the container and defines a flow passage there through, and a grippable sealing plug engaged into the passage, the tubular body having an annular outer sealing face thereon which surrounds the flow passage. The plug has a grippable formation and a sealing face surrounding the grippable formation. Claim 1 recites that the method includes the steps of supporting the tubular body of the container in a selected orientation and position, and providing a sterilization and filling head having at least an outer sealing ring thereon which is adapted to engage and seal with the annular sealing face, an inner sealing ring, and a sterilization chamber located between and at least partially defined by the outer

sealing ring and the inner sealing ring. Claim 1 recites that the method includes the steps of bringing the sterilization and filling head and the tubular body into engagement with each other so that the outer sealing ring engages and seals with the annular sealing face and the inner sealing ring engages and seals with the sealing face of the plug. In addition, claim 1 recites that the method includes the step of introducing a sterilization fluid into the sterilization chamber to sterilize at least the radially outer part of the plug and that part of the tubular body between the outer and inner sealing rings. Claim 1 also recites that the method includes the steps of gripping the grippable formation on the sealing plug and withdrawing the plug out of the tubular body in a direction away from the container whilst maintaining the outer sealing ring in sealed contact with the sealing face and the inner sealing in sealed contact with the sealing face of the plug, and introducing a flowable material into the container through the tubular body. Claim 1 also recites that the method includes the steps reinserting the plug into the tubular body to thereby close the tubular body, and disengaging the sterilization and filling head and the tubular body from each other.

Claim 4 as amended includes the additional limitation of extracting the plug from the tubular body whilst urging the inner sealing ring in sealing engagement with the sealing face on the plug.

Claim 10 as amended relates to a sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage there through and a grippable plug for closing the flow passage, at least the tubular body having an annular sealing face thereon. Claim 10 recites that the plug has a grippable formation and a sealing face surrounding the grippable formation. Claim 10 further recites that the apparatus includes holding means for holding the container and/or the tubular body in a selected position. Claim 10 also recites that the apparatus includes a sterilization and filling head having at least an outer annular sealing ring adapted to engage the annular sealing face on the tubular body and an inner sealing ring located inwardly of the outer sealing ring and adapted to engage the sealing face of the plug. The sterilization and filling head

have a sterilization chamber located inwards of and at least partially defined by the outer and inner sealing rings, the sterilization and filling head having a cavity therein adapted to receive the plug of a container to be filled, the sterilization and filling head and/or the tubular body being movable towards and away from the other.

Claim 10 further recites that the apparatus includes sterilization fluid supply means adapted to supply sterilization fluid to the sterilization chamber. Claim 10 also recites that the apparatus includes a plug extractor adapted to extract a plug from the tubular body and move the plug into the cavity in the sterilization and filling head.

Claim 10 goes on to recite that the plug extractor includes a gripper located inwardly of the inner sealing ring for gripping the grippable formation on the plug. In addition, claim 10 recites that the apparatus includes filling means adapted to fill the container through the sterilization and filling head when the plug has been extracted.

Claim 18 relates to an aseptic container adapted to be filled with a flowable material, the aseptic container having a filling opening comprising a tubular body having a flow passage there through, and a plug for sealing the flow passage.

Claim 18 recites that the plug has gripping formations on the outer face thereof, and retaining means or locking formations thereon for operatively or cooperatively locking the plug into the flow passage.

Claim 33 relates to plug and gland port for use on an aseptic container that includes a tubular body having a flow passage there through defined by a cylindrical inner wall of the tubular body, and a plug for sealing the flow passage, the plug having gripping formations on the outer face thereof, and retaining means or formations thereon for locking the plug into the flow passage. Claim 33 recites that the retaining means include an annular recess formed around the periphery of the plug, and an annular rib or lip formed around and standing proud of the cylindrical inner wall of the tubular body. In addition, claim 33 recites that the rib or lip is adapted to locate in the recess to form a locating and/or sealing engagement with the recess when the plug is operatively installed within the tubular body.

Claim 41 as amended relates to a method of aseptically filling an internally sterilized sealed container from a sterilizing and filling head through a

transfer port of the container, the transfer port comprising a tubular body sealed to a wall of the container and defining a flow passage therethrough, and a removable, sealing plug engaged in said flow passage and having a grippable formation and an annular sealing face surrounding the grippable formation, the tubular body having an exterior sealing surface, and the sterilization and filling head comprising an outer sealing ring and an inner sealing ring. Claim 41 recites that the method comprises the step of supporting the tubular body of the container in a selected orientation and position. Claim 41 also recites that the method comprises the step of bringing the sterilization and filling head into engagement with the container such that the outer sealing ring engages and seals with the sealing surface of the tubular body and the inner sealing ring engages and seals with the annular sealing face of the plug such that the inner and outer sealing rings and the portion of the transfer port extending therebetween at least partially define a sterilization chamber. Claim 41 also recites that the method comprises the step of introducing a sterilization fluid into the sterilization chamber. Claim 41 recites that the method comprises the step of gripping the grippable formation on the plug and withdrawing the plug out of the tubular body whilst maintaining the outer sealing ring in sealed contact with the tubular body and whilst maintaining the inner sealing ring in sealed contact with the sealing face of the plug. Claim 41 recites that the method comprises the step of introducing a flowable material into the container through the tubular body. Claim 41 recites that the method comprises the step of reinserting the plug into the tubular body to thereby close the tubular body. Claim 41 further recites that the method comprises the step of disengaging the sterilization and filling head from the container.

Claim 42 relates to a method of aseptically filling an internally sterilized sealed container from a sterilizing and filling head through a transfer port of the container, the transfer port comprising a tubular body sealed to a wall of the container and defining a flow passage therethrough, and a removable, grippable sealing plug sealing said flow passage, the sealing plug having a side wall engaged into the passage, the tubular body having an exterior sealing surface, the

sterilization and filling head including an outer sealing ring. Claim 42 recites that the method includes the step of supporting the tubular body of the container in a selected orientation and position. Claim 42 also recites that the method includes the step of bringing the sterilization and filling head into engagement with the container such that the outer sealing ring engages and seals with the sealing surface of the tubular body, the portion of the transfer port within the outer sealing ring providing a surface of a sterilization chamber. Claim 42 also recites that the method includes the step of introducing a sterilization fluid into the sterilization chamber to sterilize the surfaces of the sterilization chamber. Claim 42 recites that the method includes the step of withdrawing the plug out of the tubular body whilst maintaining the outer sealing ring in sealed contact with the tubular body. Claim 42 further recites that the method includes the step of introducing a flowable material into the container through the tubular body. Claim 42 recites that the method includes the step of partially reinserting the plug into the tubular body such that a portion of the plug side wall remains exposed to the sterilization chamber. Claim 42 recites that the method includes the step of cleaning the exposed surfaces of the partially inserted plug. Claim 42 recites that the method includes the step of completing the insertion of the plug into the tubular body to thereby close the tubular body. Claim 42 recites that the method includes the step of disengaging the sterilization and filling head from the container.

Claim 43 relates to a method of aseptically filling an internally sterilized sealed container from a sterilizing and filling head through a transfer port of the container, the transfer port comprising a tubular body sealed to a wall of the container and defining a flow passage therethrough, and a removable sealing plug engaged into the passage in an initial rupturable sealed position, the tubular body having an exterior sealing surface, the sterilization and filling head comprising an outer sealing ring. Claim 43 recites that the method includes the step of supporting the tubular body of the container in a selected orientation and position. Claim 43 recites that the method includes the step of bringing the sterilization and filling head into engagement with the container such that the outer sealing ring engages and

seals with the sealing surface of the tubular body, a portion of the transfer port within the outer sealing ring providing a surface of a sterilization chamber. Claim 43 recites that the method includes the step of introducing a sterilization fluid into the sterilization chamber to sterilize the surfaces of the sterilization chamber. Claim 43 also recites that the method includes the step of withdrawing the plug out of the tubular body whilst maintaining the outer sealing ring in sealed contact with the tubular body. Claim 43 also recites that the method includes the step of introducing a flowable material into the container through the tubular body. Claim 43 further recites that the method includes the step of reinserting the plug into the tubular body into a second position deeper than the initial position to thereby seal closed the tubular body. Claim 43 also recites that the method includes the step of disengaging the sterilization and filling head from the container.

Claim 44 as amended relates to a sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage therethrough and a grippable plug for sealing closed the flow passage, the tubular body having an exterior sealing surface, the plug having a grippable formation and an annular sealing face on an exterior surface of the filling nozzle. Claim 44 recites that the apparatus includes a sterilization and filling head comprising a cavity, an outer sealing ring adapted to engage the tubular body sealing surface of a container, and an inner sealing ring moveable within the cavity and adapted to engage the plug sealing face of the container, the inner and outer sealing rings at least partially defining a sterilization chamber therebetween. Claim 44 recites that the apparatus includes a sterilization fluid supply adapted to supply sterilization fluid into the sterilization chamber. Claim 44 recites that the apparatus includes a plug extractor moveable within the inner sealing ring to engage the grippable formation on the plug and to extract the engaged plug from the tubular body into the cavity whilst maintaining sealed contact between the inner sealing ring and the plug sealing face. Claim 44 recites that the apparatus includes filling means adapted to fill the container through the sterilization and filling head when the plug

has been extracted. Claim 44 recites that the apparatus includes the plug extractor further being movable to reinsert the plug into the flow passage.

Claim 49 relates to a sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage therethrough and a plug for closing the flow passage, the tubular body having an exterior sealing surface. Claim 49 recites that the apparatus includes a sterilization and filling head comprising a cavity, an outer sealing ring adapted to engage the tubular body sealing surface of a container, the outer sealing ring at least partially defining a sterilization chamber. Claim 49 recites that the apparatus includes a sterilization fluid supply adapted to supply sterilization fluid into the sterilization chamber. Claim 49 recites that the apparatus includes a plug extractor adapted to engage a plug and extract the engaged plug from the tubular body into the cavity. Claim 49 recites that the apparatus includes filling means adapted to fill the container through the sterilization and filling head when the plug has been extracted. Claim 49 recites that the plug extractor is adapted to re-insert the plug into the tubular body of a container after filling of the container into a position which is deeper than the initial position from which the plug was extracted.

Claim 51 relates to a sterilization and filling apparatus for aseptic filling of sterile containers having a filling nozzle comprising a tubular body with a flow passage therethrough and a removable sealing plug sealing said flow passage, the sealing plug having a side wall engaged into the passage, the tubular body having an exterior sealing surface. Claim 51 recites that the apparatus includes a sterilization and filling head comprising a cavity, an outer sealing ring adapted to engage the tubular body sealing surface of a container, the outer sealing ring at least partially defining a sterilization chamber. Claim 51 recites that the apparatus includes a sterilization fluid supply adapted to supply sterilization fluid into the sterilization chamber. Claim 51 recites that the apparatus includes a plug extractor adapted to engage a plug and extract the engaged plug from the tubular body into the cavity. Claim 51 recites that the apparatus includes filling means adapted to fill the container through the sterilization and filling head when the plug has been

extracted. Claim 51 also recites that the plug extractor is adapted to partially re-insert the plug sidewall into the tubular body of a container after filling of the container such that a portion of the plug side wall remains exposed to the sterilization chamber. In addition, claim 51 recites that the apparatus is configured such that whilst maintaining the plug in a partially re-inserted position the sterilization fluid supply can clean the exposed surfaces of the partially inserted plug.

Claim 52 relates to an aseptic container adapted to be filled with a flowable material from a filling and sterilization head of a filling apparatus, the aseptic container having a filling opening providing an exterior sealing surface for sterilization by the filling and sterilization head. Claim 52 recites that the filling opening includes a tubular body having a flow passage therethrough. Claim 52 also recites that the filling opening includes a plug for aseptically sealing the flow passage, the plug having at least one engageable formation adapted to be engaged by an engaging device of the filling head for removing and replacing the plug. Claim 52 recites that the filling opening includes a first rupturable seal for aseptically sealing the plug within the flow passage and for maintaining the interior of the container in an aseptic condition prior to filling. In addition, claim 52 recites that the filling opening includes a sealing and retaining formation for aseptically sealing and retaining the plug within the flow passage and for maintaining the interior of the container in an aseptic condition once filled.

Claim 54 relates to an aseptic container adapted to be filled with a flowable material from a filling and sterilization head of a filling apparatus, the aseptic container having a filling opening defining an exterior sterilizable surface for sterilization by the filling and sterilization head. Claim 54 recites that the filling opening includes a tubular body having a flow passage therethrough. Claim 54 also recites that the filling opening includes a plug for aseptically sealing the flow passage, an exterior portion of the plug being engagable by an engaging device of the filling head for removing and replacing the plug. Claim 54 recites that the filling opening includes a first sealing and retaining arrangement adapted to retain the plug in the flow passage in an initial aseptically sealed position for maintaining the interior

of the container in an aseptic condition prior to filling. Claim 54 recites that the filling opening includes a second sealing and retaining arrangement adapted to retain the plug in the flow passage in a second aseptically sealed position after the container is filled.

Dufrene purports to relate to a device for filling in a controlled atmosphere. It is respectfully submitted that Dufrene does not anticipate amended claims 1, 10, 41 and 44 for at least the reason that Dufrene fails to disclose, or even suggest, all of the limitations recited in amended claims 1, 10, 41 and 44. For instance, it is respectfully submitted that Dufrene fail to disclose, or even suggest, a plug having a grippable formation and a sealing face surrounding the grippable formation for receiving an inner sealing ring, as recited in amended claims 1, 10, 41 and 44, as well as a gripper for gripping the grippable plug. Rather, Dufrene describes a completely different arrangement whereby the cup-shaped stopper 5 is provided with an upper peripheral groove 8 which is arranged to form a clip-on fitting with a corresponding annular flange formed at the free end of a piston 19. As this clip-on fitting is in itself insufficient to withdraw the stopper, the inner piston 23 is then moved downwards to bear against the clip-on fitting and to prevent it from disengaging as the plug is withdrawn. The plug 5 in Dufrene does not include a grippable formation, but is rather held in engagement by virtue of the outwardly directed force of the inner piston 23 temporarily maintaining the integrity of the clip-on fitting or assembly. In addition, the plug is not provided with a sealing face against which an inner sealing ring engages.

In performing the connecting function, the components 8 and 19 are drawn apart by tensile forces as the plug is extracted, and could thus not also serve a sealing function. The Dufrene arrangement also necessitates the addition of a further inner piston 23 and an associated ram to assist in the interlocking process.

In contrast, in the invention as newly claimed, the sealing and plug engaging steps are separate, the inner seal is located separately relative to the gripping or extraction interface, and seals up against a sealing face on the plug which is absent from Dufrene. The integrity of the inner seal in the present invention

is complimented in the sense that the gripping jaws serve to draw the plug upwardly into more intimate contact with the inner sealing ring as the plug is extracted.

Dufrene also purports to describe in Figure 5 an arrangement in which an inwardly-disposed flange 36 on a stopper is engageable by interference with a complementary, outwardly-disposed groove 37 in the head of the piston. Thus, to the extent that Figure 5 of Dufrene discloses a grippable formation, Dufrene at most describes an arrangement in which the piston, rather than the plug, has such a formation. Moreover, the piston clearly does not disclose or suggest a "gripper" as newly claimed. In Figure 5 of Dufrene, an inner seal or plug sealing face is not necessary as the entire plug is sterilized, which is clearly not as efficient as the reduced area and volume of the sterilization chamber defined in the present invention, which is quarantined from a major portion of the outer surface of the plug. The smaller sterilization area and volume of the present invention allows the entire filling operation to be performed more quickly and efficiently.

Furthermore, it is respectfully submitted that Dufrene fail to disclose, or even suggest, the steps of partially reinserting the plug into the tubular body such that a portion of the plug side wall remains exposed to the sterilization chamber, cleaning the exposed surfaces of the partially inserted plug and completing the insertion of the plug into the tubular body to thereby close the tubular body, as recited in claim 42. Additionally, it is respectfully submitted that Dufrene fail to disclose, or even suggest, the steps of withdrawing the plug out of the tubular body whilst maintaining the outer sealing ring in sealed contact with the tubular body, introducing a flowable material into the container through the tubular body, and reinserting the plug into the tubular body into a second position deeper than the initial position to thereby seal closed the tubular body, as recited in claim 43.

In claim 44, it is specified that the plug extractor is moveable within the inner sealing ring. As was pointed out previously, this has the advantage of allowing the extractor to bear up against the inner sealing ring during the extraction process, thereby enhancing the sealed contact between the inner sealing ring and the plug sealing face. In Dufrene, as was previously been noted, the opposite effect can be

observed, in that the integrity of the seal, in so far as it exists, appears to be compromised rather than enhanced during the plug extracting process.

In addition, it is respectfully submitted that Dufrene fail to disclose, or even suggest, that a plug extractor is adapted to re-insert the plug into the tubular body of a container after filling of the container into a position which is deeper than the initial position from which the plug was extracted, as recited in claim 49. Still further, it is respectfully submitted that Dufrene fail to disclose, or even suggest, that a plug extractor is adapted to partially re-insert the plug sidewall into the tubular body of a container after filling of the container such that a portion of the plug side wall remains exposed to the sterilization chamber, wherein the apparatus is configured such that whilst maintaining the plug in a partially re-inserted position the sterilization fluid supply can clean the exposed surfaces of the partially inserted plug, as recited in claim 51. Rather, there is no description or suggestion in Dufrene to provide an arrangement in which the plug is insertable or re-insertable in more than one position, let alone a description or suggestion to provide an arrangement in which the plug is re-insertable into the tubular body to position that is different from an initial position so as to facilitate sterilization of exposed surfaces of the plug.

Furthermore, it is respectfully submitted that Dufrene fail to disclose, or even suggest, a first rupturable seal for aseptically sealing the plug within the flow passage and for maintaining the interior of the container in an aseptic condition prior to filling, and a sealing and retaining formation for aseptically sealing and retaining the plug within the flow passage, as recited in claim 52. Rather, Dufrene fails to disclose or suggest any type of seal, or sealing and retaining formation, between the plug 5 and the neck 6 of the receptacle 7 -- both being illustrated as have smooth and complementary cylindrical surfaces without having a seal of any kind therebetween -- let alone a rupturable seal that aseptically seals the plug within the flow passage and maintains the interior of the container in an aseptic condition prior to filling or a sealing and retaining formation that aseptically seals and retains the plug within the flow passage.

Furthermore, it is respectfully submitted that Dufrene fail to disclose, or even suggest, a first sealing and retaining arrangement adapted to retain the plug in the flow passage in an initial aseptically sealed position for maintaining the interior of the container in an aseptic condition prior to filling and second sealing and retaining arrangement adapted to retain the plug in the flow passage in a second aseptically sealed position after the container is filled, as recited in claim 54. Rather, and as set forth more fully above, Dufrene fails to disclose or suggest any type of sealing and retaining formation between the plug 5 and the neck 6 of the receptacle 7 -- both being illustrated as have smooth and complementary cylindrical surfaces without having a seal of any kind therebetween -- let alone first and second sealing and retaining arrangements adapted to retain the plug in the flow passage in first and second aseptically sealed positions for maintaining the interior of the container in an aseptic condition prior to, and subsequent to, filling of the container, respectively.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Dufrene do not disclose, or even suggest, all of the limitations included in claims 1, 10, 18, 33, 41 to 44, 49, 51, 52 and 54.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo, N.V. v.

U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art." See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

In summary, it is respectfully submitted that Dufrene does not anticipate claims 1, 10, 18, 33, 41 to 44, 49, 51, 52 and 54.

As for claims 3 to 9, which ultimately depend from claim 1 and therefore include all of the limitations of claim 1, claims 11 to 17, which ultimately depend from claim 10 and therefore include all of the limitations of claim 10, claims 19 to 32, which ultimately depend from claim 18 and therefore include all of the limitations of claim 18, claims 34 to 40, which ultimately depend from claim 33 and therefore include all of the limitations of claim 33, claims 45 to 48, which ultimately depend from claim 44 and therefore include all of the limitations of claim 44, claim 50, which ultimately depends from claim 49 and therefore includes all of the limitations of claim 49, claim 53, which ultimately depends from claim 52 and therefore includes all of the limitations of claim 52, and claims 55 to 60, which ultimately depend from claim 54 and therefore include all of the limitations of claim 54, it is respectfully submitted that Dufrene does not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claims 1, 10, 18, 33, 44, 49, 52 and 54, respectively.

**IV. Rejection of Claims 14, 29
and 32 Under 35 U.S.C. § 103(a)**

Claims 14, 29 and 32 were rejected under 35 U.S.C. § 103(a) as unpatentable over Dufrene. Applicants respectfully submit that Dufrene does not render obvious claims 14, 29 and 32 for the following reasons.

Applicants respectfully submit that Dufrene does not render obvious claims 14, 29 and 32 for at least the reason that Dufrene fails to disclose, or even suggest, all of the limitations recited in claims 14, 29 and 32. For example, claim 14 ultimately depends from claim 10, while claims 29 and 32 ultimately depend from claim 18. As more fully set forth above, Dufrene does not disclose or even suggest, all of the limitations recited in claims 10 and 18 for at least the reason that Dufrene fails to disclose, or even suggest, in the case of claim 18, a plug having gripping formations on an outer face thereof and retaining means or locking formations thereon for locking the plug into the flow passage. In the case of claim 10, the grippable formation, the sealing face surrounding the grippable formation and inner sealing ring and gripper located inwardly of the inner sealing ring are nowhere taught or suggested in Dufrene. The Office Action contends by Official Notice that “the use of mechanical jaws is notoriously well known in the art and it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a jaw arrangement ... in order to minimize the need for additional control circuits.” Office Action at page 5. Applicant respectfully traverses these contentions to the extent that they are maintained and request that the Examiner provide specific evidence to establish those assertions and/or contentions under 37 C.F.R. § 1.104(d)(2) or otherwise. In particular, it is respectfully requested that the Examiner provide an affidavit and/or that the Examiner provide published information concerning these assertions. This rejection is apparently being based on assertions that draw on facts within the personal knowledge of the Examiner, since no support was provided for these otherwise conclusory and unsupported assertions. (See also M.P.E.P. § 2144.03).

Moreover, judicial or official notice that is based on subjective and unsupported reasoning will not sustain an obviousness rejection. In the M.P.E.P.

cited case of In re Ahlert, 165 U.S.P.Q. 418, 420-21 (C.C.P.A. 1970)), the Court made plain that:

Assertions of technical facts in areas of esoteric technology must always be supported by citation to some reference work recognized as standard in the pertinent art and the appellant given, in the Patent Office, the opportunity to challenge the correctness of the assertion or the notoriety or repute of the cited reference. **Allegations concerning specific “knowledge” of the prior art, which might be peculiar to a particular art should also be supported and the appellant similarly given the opportunity to make a challenge.**

In re Ahlert, 165 U.S.P.Q. at 420 to 21 (citations omitted).

Otherwise, if the Examiner cannot provide either references or an affidavit to support these contentions, it is respectfully requested that the rejections of the claims under 35 U.S.C. § 103 be withdrawn for this reason alone.

To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Since Dufrene does not disclose, or even suggest, all of the limitations of claims 14, 29 and 32 as more fully set forth above, it is respectfully submitted that Dufrene does not render obvious claims 14, 29 and 32.

It is respectfully submitted that the cases of In re Fine, supra, and In re Jones, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992), make plain that the Office Action's generalized assertions that it would have been obvious to modify or combine the

references do not properly support a § 103 rejection. It is respectfully submitted that those cases make plain that the Office Action reflects a subjective "obvious to try" standard, and therefore does not reflect the proper evidence to support an obviousness rejection based on the references relied upon. In particular, the Court in the case of In re Fine stated that:

The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. This it has not done. . . .

. . . .

Instead, the Examiner relies on hindsight in reaching his obviousness determination. . . . One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

In re Fine, 5 U.S.P.Q.2d at 1598 to 1600 (citations omitted; italics in original; emphasis added). Likewise, the Court in the case of In re Jones stated that:

Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. . . .

Conspicuously missing from this record is any evidence, other than the PTO's speculation (if it be called evidence) that one of ordinary skill . . . would have been motivated to make the modifications . . . necessary to arrive at the claimed [invention].

In re Jones, 21 U.S.P.Q.2d at 1943 & 1944 (citations omitted; italics in original).

That is exactly the case here since it is believed and respectfully submitted that the present Office Action offers no evidence whatsoever, but only conclusory hindsight, reconstruction and speculation, which these cases have indicated does not constitute evidence that will support a proper obviousness finding. Unsupported assertions are not evidence as to why a person having ordinary skill in the art at the time of the invention would be motivated to modify or combine references to provide the claimed subject matter of the claims to address the problems met thereby. Accordingly, the Office must provide proper evidence of a motivation for modifying or combining the reference to provide the claimed subject matter.

More recently, the Federal Circuit in the case of In re Kotzab has made plain that even if a claim concerns a “technologically simple concept” -- which is not the case here -- there still must be some finding as to the “specific understanding or principle within the knowledge of a skilled artisan” that would motivate a person having no knowledge of the claimed subject matter to “make the combination in the manner claimed,” stating that:

In this case, the Examiner and the Board fell into the hindsight trap. The idea of a single sensor controlling multiple valves, as opposed to multiple sensors controlling multiple valves, is a technologically simple concept. With this simple concept in mind, the Patent and Trademark Office found prior art statements that in the abstract appeared to suggest the claimed limitation. But, there was no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed. In light of our holding of the absence of a motivation to combine the teachings in Evans, we conclude that the Board did not make out a proper prima facie case of obviousness in

rejecting [the] claims . . . under 35 U.S.C. Section 103(a) over Evans.

In re Kotzab, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000) (emphasis added). Again, it is believed that there have been no such findings.

Therefore, Applicants respectfully submit that Dufrene does not render obvious claims 14, 29 and 32. Withdrawal of this rejection is therefore respectfully requested.

V. Conclusion

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

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Respectfully submitted,

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